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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/967,029	09/28/2001	Keith Lurie	016354-004500US	4197

20350 7590 12/16/2003

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EXAMINER

PATEL, MITAL B

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 12/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/967,029

Applicant(s)

LURIE ET AL. *cl*

Examiner

Mital B. Patel

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5 and 7-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5 and 7-13 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/13/03 has been entered.

Response to Amendment/Arguments

2. Applicant's arguments filed 11/13/03 have been fully considered but they are not persuasive.
3. In response to Applicant's argument that claim 1 is amended to include the recitation "lowering the intrathoracic pressure by spontaneous breathing of the patient while preventing or inhibiting respiratory gas flow to the lungs..." it should be noted that there would be some spontaneous breathing by the patient either through the nose or the mouth.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 5, 7, 8, 9, 10, 11, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lurie et al (US 5,692,498) in view of Lurie et al (US 5,588,422).

6. **As to claim 1**, Lurie et al (US 5,692,498) teach a method for administering a drug to a patient, the method comprising coupling a valve system **108** to the patient's airway, wherein the valve system is configured to prevent or impede respiratory gases from flowing into the lungs until a magnitude of a threshold negative intrathoracic pressure in the range from 0 cm H₂O to about 40 cm H₂O is exceeded (**Col. 14, lines 33-59**); lowering the intrathoracic pressure by spontaneous breathing of the patient while preventing or inhibiting respiratory gas flow to the lungs with the valve system to cause blood to flow into the thorax and thereby increasing vital organ perfusion to enhance circulation of the drug (**Col. 13, lines 8-24**). Lurie et al (5,692,498) fail to specifically teach introducing a drug into the patient. However, Lurie et al (US 5,588,422) does teach the use of introducing a drug into a patient in conjunction with CPR in order to enhance patient survival and reduce heart and brain damage. Therefore, it would have been obvious to one of ordinary skill in the art to introduce a drug in conjunction with the CPR valving system of Lurie et al (5,692,498) in order to enhance patient survival and reduce heart and brain damage.

7. **As to claim 5**, the above combination teaches a method wherein the intrathoracic pressure is reduced by squeezing the chest and relaxing the chest with a

chest caress **Col.3, line 50** while preventing or inhibiting airflow to the lungs with the valve system

8. **As to claim 7**, the above combination teaches a method wherein the drug is administered by a process selected from a group consisting of intravenously, through the patient's bone, through the patient's airway, orally, nasally, endobronchially, rectally, and transdermally.

9. **As to claim 8**, the above combination teaches a method wherein the drug is administered through a facial mask or the valve system **Col. 5, lines 5-11**.

10. **As to claim 9**, the above combination teaches a method wherein the drugs are selected from a group consisting of glucose, sodium bicarbonate, oxygen, steroids, vasopressor drugs, anti-arrhythmic drugs, anti-seizure, anti-asthma, anesthetics, and cooling solutions to cool the brain during cardiac arrest.

11. **As to claim 10**, the above combination teaches a method wherein the valve system is configured to permit respiratory gases to exit the patient's lungs, and further comprising forcing respiratory gases from the lungs and out the valve system.

12. **As to claim 11**, the above combination teaches a method wherein the valve system is configured to prevent respiratory gases from exiting the patient's lungs until a positive end expiratory pressure in the range from about 0 cm H₂O to about 20 cm H₂O is exceeded.

13. **As to claim 12**, the above combination teaches a method wherein the valve system is coupled to a facial mask that is placed over the mouth and nose, and further comprising removing the drug from the drug storage compartment of the facial mask.

14. **As to claim 13**, the above combination teaches a method wherein the valve system is coupled to an inhalation device that includes the drug, and further comprising inhaling from the inhalation device to administer the drug.

Allowable Subject Matter

15. Claims 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 703-306-5444. The examiner can normally be reached on Monday-Friday (8:00 - 4:30).

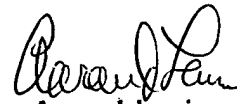
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

mbp

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Aaron J. Lewis
Primary Examiner